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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/391,861	09/07/1999	ARLEN READ THOMASON	99.371	9209

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/391,861	THOMASON ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,39,41-43 and 49-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-12,39,41 and 49-52* is/are rejected.

7)☒ Claim(s) *5,7,42,43,53 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Group and/or Art Unit designation of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Primary Examiner Scott D. Priebe, Ph.D., Group Art Unit 1633.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 13 and 49-54 are objected to because of the following informalities. These claims do not comply with 37 CFR 1.121(c). Claim 13 has been cancelled, and not "currently amended" as recited. Also, no text should be presented for a cancelled claim. See §121(c) & (c)(4)(i). New claims 49-54 should not be underlined, see §121(c)(3). Applicant must provide a new claim listing that fully complies with §121(c), regardless of whether any new amendments are made. Appropriate correction is required.

Claims 5, 7, 42, 43, 53, and 54 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from another multiple dependent claim and must depend from the multiple claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. It is noted that claims 5, 7, 42, and 43 had previously been treated further on the merits, which was improper. This oversight is corrected here, and the rejection of these claims has been withdrawn. If the improper dependency is corrected, the previous grounds of rejection will be reinstated where applicable.

Applicant asserts that the amendments to the claims have overcome this objection. However, claim 5 has not been amended (nor has claim 2, which is still multiply dependent). The amendment to claim 42 only corrects the dependence on another multiply-dependent claim. Claims 5, 42, and 53, and their dependent claims, depend from multiple claims in other than the alternative, which is improper.

Claim Rejections - 35 USC § 101

Claims 1-6, 7-13, 39, and 41-43 remain rejected and claims 49-52 are rejected under 35 U.S.C. 101 for the reasons of record set forth in the Office action of 12/2/05, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-6, 7-13, 39, and 41-43 remain rejected and claims 49-52 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 6/2/06 have been fully considered but they are not persuasive. Applicant (Reply, page 7) identifies what little information the specification provides about the nature of the "FGF-like" polypeptide of the invention, and asserts that one of skill in the art would correlate with a utility asserted in the specification. In response, each of these teachings have been addressed in the grounds of rejection, and their inadequacy to disclose a specific and substantial utility has been addressed by scientific reasoning and evidence.

Applicant (Reply , pages 7-8) argues that the decisions in *Brenner* and *Kirk* do not apply to the instant case, because it does not "offend public policy". Applicant asserts, without explanation, that the claimed invention "would not hinder research of other FGF family members" nor " broadly prevent anyone from discovering other FGF family members". In response, as admitted by Applicant one issue in *Brenner* was that the claims in question would "inhibit others from searching for uses of those compounds". As set forth in the rejection, the instant specification does not disclose a single specific and substantial use for the claimed invention that provides specific benefit in a currently available form. Rather, the specification lists, for example, a variety of unrelated diseases that the instant invention "may" be useful in diagnosing or treating. Such disclosure is nothing more than an invitation to one of skill in the art to go out and determine for which, if any, of these diseases the claimed invention might be useful in diagnosing or treating. Furthermore, the claims are directed to a genus (see, e.g. claim 1), that potentially embraces other naturally-occurring FGF family members, and certainly embraces structural variants of the species disclosed that may or may not have the same activity, and therefor uses, as the disclosed species. Consequently, the claimed invention would have the effect of hindering research on other FGF-like polypeptides and FGF family members than the species disclosed in the instant application.

Applicant (Reply, page 9-10) argues that the phenotype observed for a mouse that ectopically overexpressed the FGF-like polypeptide would somehow suggest to one of skill in the art that the polypeptide would be useful in affecting the weight of an animal. In response, the observed phenotype of these mice was addressed in the rejection, as was the inadequacy of this evidence to convey a use that would provide immediate benefit to the public. These mice

suffered from hypertrophy of several different organs, it is hardly surprising that they weighed less than normal age-matched mice. It is unclear how one of skill in the art could be expected to comprehend the specific and substantial use of a polypeptide that causes developmental organ abnormalities in mice when expressed inappropriately during development. Despite the liver hypertrophy of these mice, the specification suggests that the FGF-like polypeptide "may" "stimulate" liver tissue *inter alia.* This and other contradictions in the specification, such as the teaching that both the FGF-like polypeptide and its inhibitors would be useful for treating the same diseases, illustrate that the specification does not provide a specific and substantial use for the claimed invention but simply lists a variety of possible uses, in the hope that at least one of them might prove true.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 8, 9, 11, and 39 remain rejected and claims 49, 50, and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Acc. No. AQ175436, 10/17/98, as evidenced by Kennel, D.E. (Progr. Nucl. Acid Res. Mol. Biol. 11: 259-301, 1971) with respect to claim 1 and dependents, for the reasons of record set forth in the Office action of 12/2/05.

Claims 1 and 39 remain rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Acc. No. AV050323, 6/22/99, as evidenced by Kennel, D.E. (Progr. Nucl. Acid Res. Mol. Biol. 11: 259-301, 1971) with respect to claim 1 and dependents, for the reasons of record set forth in the Office action of 12/2/05.

Claims 2, 4, 8, 9, and 11 remain rejected and claims 49, 50, and 51 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GenBank Acc. No. AV050323, 6/22/99, as evidenced by Kennel, D.E. (Progr. Nucl. Acid Res. Mol. Biol. 11: 259-301, 1971) with respect to claims dependent from claim 1, and GenBank Acc. No. AQ175436, for the reasons of record set forth in the Office action of 12/2/05.

Claims 1-4, 8-11, 13, 39, and 41 remain rejected and claims 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards et al., US 6,639,063, in claiming priority to 60/147,499, filed 8/5/99, for the reasons of record set forth in the Office action of 12/2/05.

Applicant's arguments filed 6/2/06 have been fully considered but they are not persuasive. First, Applicant's arguments rely primarily on a Niyogi reference, which has not been provided to the PTO. Consequently, arguments pertaining to this reference have not been considered and are moot.

It is respectfully submitted that the hybridization and wash conditions recited in claim 1 are not high stringency, as Applicant appears to be arguing. The conditions in claim 1 (1) are wash conditions, and at this osmolarity, high stringency conditions generally would be carried out at 65-68°C, depending on the G/C content of the expected homoduplex, not at 50°C. The conditions recited in part (2) are carried out in formamide, which does not increase the stringency, as applicant alleges, nucleic acid duplexes simply have a lower melting temperature in formamide. This allows one to carry out hybridization and wash conditions at a lower temperature than in the absence of formamide. The hybridization conditions recited are carried in

5XSSC, which is not high stringency, even in formamide at 42 °C. Also, claim 39 and its dependent claims require only minimum lengths of identical nucleotides or nucleotides that encode a length of identical amino acids, not hybridization conditions, which are met byu the prior art.

Finally, Applicant appears to misunderstand the nature of hybridization stringency and their relation to the teachings of Kennell. The level of stringency of hybridization conditions, e.g. high, medium, low, etc., is an indication of how close to the melting temperature, Tm, of the homoduplex formed by the probe and its complement, e.g. SEQ ID NO: 1 or SEQ ID NO: 3, the hybridization is carried out. High stringency conditions are those that are generally between 5-10 °C below the Tm of the homoduplex at a given osmolarity and pH, (and formamide concentration, if used). The level of stringency used is determined by the sequence similarity between the probe and the target. What Kennell teaches is that a homoduplex of 25 nucleotides (for all G-C basepairs) to 50 nucleotides (for all A-T nucleotides) is nearly as stable, i.e. has nearly the same Tm, as a homoduplex of much longer length that contains the shorter duplex. This is independent of the hybridization stringency conditions. Consequently, the Tm for a given homoduplex longer than this 25-50 nucleotide threshold is determined by the Tm of the most stable region of the homoduplex, i.e. the stability of the last 25-50 nucleotides (depending on G-C content) that dissociate (or melt). As indicated in the rejections, the contiguous homoduplexes that would form between SEQ ID NO: 1 or 3 and the prior art sequences are longer than 50 nucleotides, and in two cases substantially longer. In other words, the duplexes formed between the prior art sequences and SEQ ID NO: 1 or 3 would have the same or nearly the same Tm as would SEQ ID NO: 1 or 3 and its complement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633